Remarks/Arguments

Favorable consideration of this application is respectfully requested in view of the above amendment and the following remarks. Entry of this amendment is respectfully requested. A Notice of Appeal is enclosed with this amendment.

Claims 1-11 and 13-19 are pending in the application. Claims 1-11 and 13-19 have been rejected. Claims 17-19 have been cancelled without prejudice. New claims 20 and 21 has been added. Support for the language in new claim 20 can be found in the originally filed claims and in the specification, e.g., the paragraph bridging pages 2-3 and page 3, lines 12-39. Support for the language in claim 21 can be found in the specification, e.g., page 12, lines 30-34. It is submitted that no new matter has been added.

Claims 1-11 and 13-16 have been rejected under 35 U.S.C. §102(b) as being anticipated by EP0876815 (EP'815). With respect to EP'815 the Examiner states *inter alia*:

> "A reference may be relied on for all it teaches, and is not limited by preferred embodiments or examples. EP'815 clearly teaches embodiments wherein the concentration of the progestogenic compound is about one times the saturation level, and further teaches the importance of keeping the compound dissolved in a low concentration to improve the shelf life. The skilled practitioner would instantly envision values at or just under the saturation level to afford a product with a prolonged shelf life. The teaching of EP'815 meets every limitation of the instant claims."

Applicants respectfully disagree with the Examiner's conclusion and submit that claims 1-11 and 13-16 are not anticipated by EP'815 for the reasons stated below.

As is well established, in order to anticipate a later claim, a single prior source must contain all of the essential limitations of the claim. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1379 [231 USPQ 81] (Fed. Cir. 1986) ("for prior art to anticipate under §102 it has to meet every element of the claimed invention"), *cert. denied,* 480 U.S. 947, 107 S.Ct. 1606 (1987).

In the present case, it is asserted that the EP'815 drug delivery system (DDS) does not contain all of the essential limitations of the presently claimed DDS. With respect to EP'815, this reference makes clear throughout its disclosure that the progestogenic compound is dissolved in the core polymer in a low degree of supersaturation (see page 2 line 58 wherein it states "said progestogenic compound being initially dissolved in the core polymer in a relatively low degree of supersaturation; page 3, lines 12-13 wherein it states "...the present invention is based on the surprising finding that a steroid can be retained in a supersaturated sate during prolonged storage..."; page 4, lines 54-55 wherein it states "This example shows that even with etonogestrel at a relatively low degree of supersaturation, a stable dosage form can be obtained"; page 6, claim 1, line 28, wherein it states "...said progestogenic compound being initially dissolved in the said polymer core material in a relatively low degree of supersaturation,..."). Indeed, EP'815 on page 4, lines 6-7 indicates that it is an essential element of the present invention to have the progestogenic steroid dissolved in the core material in a relatively low degree of supersaturation.

While EP'815 at claim 4 indicates that the progestogenic compound is dissolved in the thermoplastic core material in an amount by weight of at least about one but not more than about 6 times the amount necessary for obtaining its saturation concentration, the fact remains that in the EP'815 DDS, it is an absolute requirement that the progestogenic compound be dissolved in the core in a relatively low degree of supersaturation (note that claim 4 depends from claim 1 which requires the essential element of low degree of supersaturation of the progestogenic compound in the core.). Even a relatively low degree of supersaturation is still a degree of supersaturation.

In contrast to EP'815, the presently claimed DDS requires as an essential element that the progestogenic compound be dissolved in the polyethylene vinylacetate copolymer up to a concentration below the saturation level at 25°C. Accordingly, the essential element of the present invention is not identically described in the EP'815 reference.

As stated above, the Examiner contends that the EP'815 teaches the importance of keeping the compound dissolved in a low concentration to improve the shelf life, and that one skilled in the art would instantly envision values at or just under the saturation level to afford a product with a prolonged shelf life. Contrary to the Examiner's contention, Applicants assert that one skilled in the art reading EP'815 would not envision values below the saturation level for the following reasons.

In addition to the reference's emphasis that the progestogenic compound be present in the polymer core at a low degree of supersaturation, EP'815 indicates that the steroid may be retained in such a supersaturated state during prolonged storage of the DDS at temperatures between 4°C and 25°C. The present specification also indicates that the EP'815 DDS is physically stable only when stored below room temperature (see present specification, page 2, line 29-36), whereas the presently claimed DDS is physically stable when stored on or above room temperature (see present specification, the paragraph bridging pages 2-3 and page 3, lines 36-39). There is not the slightest hint in the EP'815 reference of utilizing a progestogenic compound below the saturation level or that such level below saturation would make for a difference in the physically stability of the presently claimed DDS compared with the EP'815 DDS when stored on or above room temperature. Accordingly, since 1) EP'815 requires that the progestogenic compound present in the polymer core is in a state of "supersaturation", and 2) the EP'815 DDS requires storage between 4°C and 25°C, how would one skilled in the art envision 1) utilizing in a DDS a progestogenic compound at a concentration below the saturation level, or 2) that such a change in the progestogenic compound concentration would yield an improved DDS having the property of being physically stable when stored on or above room temperature. In view of the above, it is believed that EP'815 does not meet every limitation of the presently claimed DDS and the presently claimed DDS is not identical to the EP'815 DDS. Accordingly, the presently claimed DDS is not anticipated by EP'815.

It is further submitted that new claim 20 (dependent on claim 1) directed to a DDS which further recites the feature "...wherein the DDS is physically stable when stored on or above room temperature" is patentable over EP'815 as the EP'815 DDS is not identical nor possesses the aforementioned feature exhibited by the presently claimed DDS.

In view of the above, withdrawal of the rejection of claims 1-16 under 35 U.S.C. §102(b) is respectfully requested.

Claims 17-19 have been objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. As claims 17-19 have been cancelled without prejudice, this rejection no longer applies.

In view of the above, withdrawal of the objection to claims 17-19 is respectfully requested.

Claims 17-19 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite in the recitation of "between 0.1 and 1.0 wt%". Since claims 17-19 have been cancelled without prejudice, this rejection no longer applies.

In view of the above, withdrawal of the rejection of claims 17-19 under 35 U.S.C. §112, second paragraph, is respectfully requested.

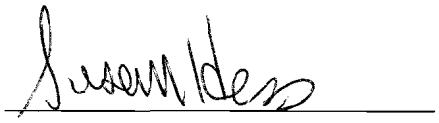
Claims 17-19 have been rejected under 35 U.S.C. §102(b) as being anticipated by van Laarhoven et al., International J. of Pharmaceutics, 2002, 232, 163-173). Since claims 17-19 have been cancelled without prejudice, this rejection no longer applies.

In view of the above, withdrawal of the rejection of claims 17-19 under 35 U.S.C. §102(b) is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, he is requested to call the undersigned at the number listed below.

Dated: May 19, 2009

Respectfully submitted,

By 

Susan Hess
Registration No.: 37,350
Attorney For Applicant(s)

Organon International Inc.
Patent Department
c/o Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey
K-6-1; MS 1990
Tel: (908) 298-2161
Fax: (908)-298-5388

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